Covid-19: Pfizer asks US regulator to authorise fourth vaccine dose for over 65s

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Pfizer and BioNTech have applied to the US Food and Drug Administration for emergency use authorisation for a fourth dose of its mRNA vaccine against covid-19 for adults aged 65 and older.

The companies said that the additional dose reduced the rates of infection and severe illness in older adults. In a press release they said that they were seeking the new approval for adults over 65 who had received an initial booster of any of the authorised or approved covid-19 vaccines.1

Pfizer-BioNTech said that the request was based on “two real-world data sets from Israel analyzed at a time when the Omicron variant was widely circulating. These data showed evidence that an additional mRNA booster increases immunogenicity and lowers rates of confirmed infections and severe illness.”

The companies said that an analysis of Israeli Ministry of Health records was conducted on over 1.1 million adults aged 60 and over who had no known history of SARS-CoV-2 infection and were eligible for a fourth vaccine dose. They wrote, “These data showed rates of confirmed infections were two times lower and rates of severe illness were four times lower among individuals who received an additional booster dose of the Pfizer-BioNTech covid-19 vaccine administered at least four months after an initial booster (third) dose compared to those who received only one booster dose.”

The submission to the FDA also included results from an ongoing, open label, non-randomised clinical trial in healthcare workers aged 18 and over at a single study centre in Israel who had been vaccinated with three doses of the Pfizer-BioNTech vaccine, the companies’ press release stated.

It said that the data from Israel being reviewed by FDA suggested that an additional (fourth) booster dose, administered at least four months after the booster, “could restore antibody titers to peak post-third dose titer levels, improve protection against both infection and severe disease in individuals 60 years of age and older in Israel, and have a similar safety profile to that of previous doses.” The data come from a study published in a preprint server, which has not been peer reviewed.2

Pfizer’s chief executive, Albert Bourla, said on CBS television that the protection from the third dose was “actually quite good for hospitalisations and deaths. It’s not that good against infections [and] doesn’t last very long.” He said that a fourth dose was needed as the omicron variant continued to spread and that the Centers for Disease Control and Prevention had found that booster shots lost much of their effectiveness after four months.3

Effects of fourth dose

Stephen Hoge, president of Moderna, which produces the other approved mRNA vaccine, told Business Insider that he would encourage a fourth dose of the Moderna vaccine for people over 50 and for immunocompromised individuals. He said that it would not be necessary for the general public, although it might be beneficial.3

On 16 March a research letter published in the New England Journal of Medicine reported the effects of using either Pfizer or Moderna vaccines as a fourth vaccine dose in 174 healthcare workers in Israel, given four months after a booster dose. Each participant was matched to two controls.4

Overall, 25% of the control group were infected with the omicron variant, compared with 18.3% of participants given a Pfizer fourth dose and 20.7% of those given Moderna. Vaccine efficacy against any SARS-CoV-2 infection was 39% (95% confidence interval −9% to +55%) with the Pfizer vaccines and 11% (−43% to +44%) with Moderna.

The researchers reported that most of the participants infected with omicron in either the treatment or control groups reported negligible symptoms but were potentially infectious, with relatively high viral loads. The team concluded that in healthy young people a fourth vaccination might have only marginal benefits.

Commenting on the study, Paul Hunter, professor in medicine at the University of East Anglia, UK, said, “To my mind the implications of this study are that we shouldn’t rush to broaden the rollout of the current plans for a fourth dose in the UK, though I would still progress with what is currently planned for our most vulnerable groups.

“Hopefully by the autumn we will have a better understanding about the potential value of further boosters a year after the third dose. Future rollouts of vaccine boosters on an annual or less frequent basis do need to be proven to have value before being implemented.”

The FDA’s vaccine advisory committee will meet in April to consider the request from Pfizer-BioNTech. Moderna has not asked FDA for approval of a fourth dose but is reported to be investigating a booster that targets the omicron variant.5

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Veser N. Moderna president says 4th vaccine dose beneficial, but not necessary for all. Huffington Post 2022 Mar 15. https://www.huffpost.com/entry/moderna-4th-vaccine-dose_n_622fe22be4b0fe0944da5f74


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